REMARKS

I. Introduction

This application is a continuation of parent application No. 09/850,021, filed May 7, 2001. Claims 1-11, as originally filed, had been pending in the parent application (as claims 1-5 and 7-12). Claim 1 has been amended to more particularly define the invention.

The specification has been amended to add a cross reference to the parent application and to update the status of an incorporated reference.

II. History of Claims 1-11 in the Parent Application

Claims 1-11, as originally filed, were variously rejected in a May 14, 2003 Office action issued in the parent application. More specifically, claims 1-11 were rejected under 35 U.S.C. § 112, first paragraph as containing subject matter that is not supported by the written description. Claims 1-6 and 8-11 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Dakov U.S. patent 6,030,392 (hereinafter "Dakov"). Claim 7 was rejected under 35 U.S.C. § 103(a) as being unpatentable over Dakov in view of van der Gaast U.S. patent 3,577,979 (hereinafter "van der Gaast"). Claims 1-6 and 8-11 were rejected under 35 U.S.C. § 102(b) as being anticipated by or, in the alternative, under 35 U.S.C. § 103(a) as being unpatentable over Kornberg et al. U.S. patent 5,353,804 (hereinafter "Kornberg"). Claim 7 was rejected

under 35 U.S.C. § 103(a) as being unpatentable over Kornberg in view of van der Gaast.

The Examiner's rejections of claims 1-11 in the May 14, 2003 Office action of the parent application will be addressed below.

III. Remarks on the Rejections of Claims 1-11 in the May 14, 2003 Office Action of the Parent Application

Applicants' independent claim 1, as originally filed, is directed toward an apparatus for cutting an aperture in a side wall of a patient's blood vessel. The apparatus includes a tissue-piercing structure with a longitudinal axis that is configured to pierce the side wall of the blood vessel. A plurality of resilient structures are mounted on the tissue-piercing structure so that they do not substantially increase the dimensions of the tissue-piercing structure transverse to its longitudinal axis as it passes through the side wall. The resilient structures are resiliently biased to spring radially outwardly from the tissue-piercing structure after the tissue-piercing structure and the resilient structures have passed through the side wall. A hollow annular tissue-cutter structure is disposed annularly around the tissue-piercing structure and is configured for movement parallel to, and for rotation about the longitudinal axis of the tissue-piercing structure to produce an annular cut through the side wall. The tissue-cutter structure thereby severs a disc of tissue from the side wall that was

previously pierced by, and that remains impaled on the tissue-piercing structure. The outwardly sprung resilient structures serve to at least help hold the disc of cut tissue on the tissue-piercing structure.

Applicants have amended claim 1 in order to more particularly define the invention. Claim 1, as amended, further sets forth the feature of applicants' invention that the tissue-piercing structure independently passes through all of the tissue to be pierced without any external means of support. Support for this amendment to claim 1 can be found in applicants' FIGS. 1A-1C, FIG. 2, and the written description accompanying those FIGS. Accordingly, no new matter has been added.

A. The Rejection of Claims 1-11 under 35 U.S.C. § 112, First Paragraph

In the May 14, 2003 Office action, the Examiner rejected originally filed claims 1-11 under 35 U.S.C. § 112, first paragraph as containing subject matter that is not supported by the written description. This rejection is respectfully traversed.

Specifically, the Examiner contends that there is no basis in the original parent application (application No. 09/014,759, filed January 28, 1998, from which both the parent application and the present application claim priority) for the feature set forth in applicants' claim 1 that "outwardly sprung resilient structures" mounted on the tissue-piercing structure "serv[e] to at least help hold

the disc" of tissue cut from the side wall of the patient's blood vessel "on the tissue-piercing structure" (lines 23-26 of claim 1). Contrary to the Examiner's contention, applicants submit that the disclosure of said original parent application fully supports this feature of applicants' claim 1.

The Examiner contends that "there is no indication that once the tissue disc 60 is formed by being cut from the surrounding tissue, it is held on the wire 30 by the barbs 55" because the tissue disc is shown "being retained within the cutting head 45 where it is incapable of contacting barbs 55" (page 2, lines 11-22 of May 14 Office action).

Contrary to the Examiner's contention, applicants' original disclosure describes struts 55 as being "resiliently biased to project from the centering wire after the end portion of the centering wire pierces through body organ structure 1 to prevent the centering wire from passing back through body organ structure 1" (page 6, lines 15-28 of applicants' specification). This retaining function of struts 55 expressly teaches that struts 55 prevent the tissue surrounding the centering wire, which is pierced by the centering wire, from passing over the distal end of the centering wire. Further, the resilient nature of struts 55 when sprung outwardly conveys that the retaining function of struts 55 is operative both

before and after the tissue surrounding the centering wire is cut from the side wall.

In addition to the foregoing, although the Examiner correctly points out that one illustrative example of applicants' specification describes tissue disc 60 being accepted within an axially aligned recess in cutting head 45, this illustrative example does not contradict or dismiss the role of retaining features such as struts 55 and the hooked distal end of centering wire 30 in preventing the tissue disc from sliding distally off the end of the centering wire (see FIGS. 3 and 4 of applicants' specification). To the contrary, in view of the extremely undesirable result of the tissue disc sliding off the centering wire and possibly becoming lost within the patient, the consequences of which are well known in the art, applicants submit that one of ordinary skill in the art would understand from applicants' original disclosure that multiple, redundant means (struts 55, axial recess of cutting head 45, hooked distal end of centering wire 30, etc.) exist in applicants' invention to help hold the tissue disc on the centering wire.

Further, applicants note that the figures of the original disclosure are schematic in nature and do not attempt to show every detail or every possible disposition of the elements illustrated therein. However, applicants submit that FIG. 1C, along with its accompanying description (page 6, lines 8-34 of applicants'

specification), clearly illustrates the retaining function of struts 55 in a manner that would convey to one of ordinary skill in the art the function of struts 55 in preventing the disc of cut tissue surrounding centering wire 30 from sliding distally off the centering wire. Applicants submit that the retaining function of struts 55, both before and after the disc of tissue is cut from the side wall, is a feature of applicants' apparatus that would be clearly understood by one of ordinary skill in the art to exist in applicants' original disclosure.

Therefore, applicants submit that the disclosure of the original parent application fully supports applicants' claimed feature of outwardly sprung resilient structures, mounted on the tissue-piercing structure, that serve to at least help hold the tissue disc on the tissue-piercing structure. Accordingly, applicants respectfully submit that claims 1-11 satisfy the written description requirement of 35 U.S.C. § 112, first paragraph.

B. The 35 U.S.C. § 103(a) Rejection over Dakov

In the May 14, 2003 Office action, the Examiner rejected originally filed claims 1-6 and 8-11 under 35 U.S.C. § 103(a) as being unpatentable over Dakov. This rejection is respectfully traversed.

Dakov shows cutting instrument 400 that creates a side opening in a hollow tubular organ. The cutting

instrument includes rigid rod 402 and cutting cylinder 410 with sharp lower edge 412. Cutting cylinder 410 is slideably and coaxially positioned over rod 402. Shaft 406, which ends with pointed and barbed end 408, is affixed axially to the lower end of rod 402. In use, rod 402 is pushed down so that barbed end 408 of shaft 406 pierces the wall of the hollow organ. Cutting cylinder 410 is then slid down over rod 402 so that sharp edge 412 of the cutting cylinder cuts out a portion of the side wall of the hollow organ.

Applicants submit that applicants' independent claim 1 is patentable over Dakov because Dakov fails to show or suggest all the features of claim 1. Applicants' independent claim 1 sets forth "a hollow annular tissue-cutter structure disposed annularly around [a] tissue-piercing structure and configured for movement substantially parallel to the longitudinal axis [of the tissue-piercing structure] and for rotation about the longitudinal axis to produce an annular cut through the side wall" (lines 17-21 of applicants' claim 1). Applicants submit that Dakov fails to show or even suggest applicants' claimed feature of rotating the tissue-cutter structure to produce an annular cut in the side wall. Instead, Dakov only shows a cutting cylinder 410 which is "slided [sic] down while the basic rod 402 is held in a stable position" (column 14, lines 8-9 of Dakov).

The Examiner contends that Dakov shows the rotational cutting feature of applicants' invention because "[t]he entire apparatus shown in figures 30-33 of Dakov, (including the tissue-cutter structure and the tissue-piercing structure) is clearly configured for rotation about the longitudinal axis of the tissue-piercing structure by, for example, manually rotating the entire apparatus" (page 6, lines 15-19 of May 14 Office action). Applicants submit that this contention is erroneous because there is not a single showing or suggestion in Dakov of rotating cutting cylinder 410, either by itself or along with "the entire apparatus."

The Examiner further contends that "[i]n any event, it is well known in the surgical arts to rotate a circular cutter as it is advanced in order to enhance the tissue cutting action on tissue" (page 7, lines 5-8 of May 14 Office action). Applicants submit that this contention also fails because there is no suggestion or motivation, either in Dakov or the knowledge generally available to one of ordinary skill in the art, to modify Dakov's apparatus to cut by rotation of its cutting cylinder. To the contrary, Dakov distinctly teaches away from the rotational cutting feature of applicants' invention when Dakov teaches that "instruments that cut out an oval, ellipsoid, or other side openings can be constructed in a similar manner" as cutting instrument 400 (column 14, lines 14-15 of Dakov). Dakov's entire description of cutting instrument 400 only

shows tissue cutting by sliding cutting cylinder 410 down over rod 402. Since tissue cutting by rotation of a non-circular cross-section cutting cylinder poses unique challenges not addressed by Dakov, Dakov's teaching that non-circular openings can be cut using instruments constructed in the same manner as instrument 400 (i.e., cutting cylinder 410 and rod 402 with the same cross-sectional shape) clearly teaches away from any modification for rotational cutting by providing an affirmative reason to retain the original configuration.

Applicants further submit that there is no objective evidence of any motivation or suggestion in the knowledge generally available to one of ordinary skill in the art to modify Dakov for rotational cutting. The Examiner points to van der Gaast and Kornberg, which show biopsy apparatus that may be rotated during cutting, as examples of the ordinary skill in the art. However, applicants submit that the mere fact that a modification is within the ordinary skill in the art is insufficient to establish a prima facie case of obviousness without objective evidence of a suggestion or motivation to make the modification. The level of skill in the art, as pointed to by the Examiner, cannot be relied upon to provide the suggestion to modify Dakov. Applicants submit that the Examiner failed to provide objective evidence of a suggestion or motivation in the general art to modify Dakov, a reference which not only fails to provide any

suggestion for the proposed modification, but distinctly teaches away from the modification. Therefore, applicants submit that the Examiner's proposed modification of Dakov is based upon an impermissible reconstruction of applicants' invention that is motivated by hindsight.

Applicants further submit that the Examiner's proposed modification of Dakov for rotational cutting would alter the principle of operation for the Dakov cutting instrument and render it unsatisfactory for its intended purpose. The Dakov cutting instrument uses a linear cutting motion without rotation to accommodate cutters of non-circular cross sections. The Examiner's proposed modification of Dakov would render its cutting instrument inoperable for non-circular cross-sections and thereby change the principle of operation of the Dakov cutting instrument. Therefore, applicants submit that the teachings of Dakov cannot be sufficient to render applicants' invention obvious.

Accordingly, for at least the foregoing reasons, applicants respectfully submit that independent claim 1 and dependent claims 2-6 and 8-11 are patentable over Dakov.

C. The 35 U.S.C. § 102(b)/§ 103(a) Rejections over Kornberg

In the May 14, 2003 Office action, the Examiner rejected originally filed claims 1-6 and 8-11 under 35 U.S.C. § 102(b) as being anticipated by or, in the alternative, under 35 U.S.C. § 103(a) as being unpatentable

over Kornberg. This rejection is respectfully traversed in view of amended independent claim 1.

Kornberg shows a biopsy tool for removing suspect breast tissue. The apparatus includes hollow cylindrical cannula 2 with sharp cutting surface 5 at its distal end. A cylindrical stylet 6 fits within the cannula and has a tapered distal end. The stylet has a hollow central shaft through which localizing needle 20 can pass. The localizing needle is also hollow and allows guide wire 23 to be passed through. In use, Kornberg shows first implanting localizing needle 20 into the patient's tissue to the site of the abnormality, and then passing guide wire 23 through the hollow of the localizing needle to be anchored at the desired site.

Applicants submit that independent claim 1, as amended, is patentable over Kornberg at least because Kornberg fails to disclose or even suggest a plurality of resilient structures mounted on a tissue-piercing structure configured to pierce the side wall of a blood vessel by independently passing through all of the tissue to be pierced without any external means of support.

Specifically, Kornberg fails to disclose or suggest that guide wire 23, on which barbs 24 are mounted, is configured to pass through all of the patient's tissue to be pierced without any external means of support. To the contrary, FIG. 2 of Kornberg shows that hollow localizing needle 20 first pierces through the patient's

tissue and passes to the desired location distal of the abnormality. Guide wire 23 is then merely inserted through the central hollow of localizing needle 20 until its hooked end 24 passes out of the distal end of needle 20, whereupon "hooked end 24 immediately expands to anchor itself in the surrounding tissue" (column 7, lines 41-44 of Kornberg).

Applicants' further submit that there is no suggestion or motivation, in either Kornberg or the general knowledge of the art, to modify Kornberg to meet this feature of claim 1. To the contrary, the Kornberg apparatus actually teaches away from the independent tissue-piercing structure of applicants' invention by providing a separate localizing needle for piercing through the patient's tissue.

Accordingly, for at least these reasons, applicants respectfully submit that amended independent claim 1 and dependent claims 2-6 and 8-11 are patentable over Kornberg.

C. The 35 U.S.C. § 103(a) Rejections of Claim 7

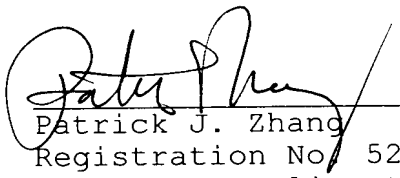
In the May 14, 2003 Office action, the Examiner rejected claim 7 under 35 U.S.C. § 103(a) as being unpatentable over Dakov in view of van der Gaast. The Examiner also rejected claim 7 under 35 U.S.C. § 103(a) as being unpatentable over Kornberg in view of van der Gaast. Applicants submit that dependent claim 7 is patentable at least because the foregoing remarks demonstrate that

currently amended independent claim 1, from which claim 7 depends, is patentable.

IV. Conclusion

In view of the foregoing, applicants submit that this application is in condition for allowance. An early and favorable action is respectfully requested.

Respectfully submitted,



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